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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/505,393 | 08/20/2004 | Mitsuaki Kuwano | 04561/HG | 7247 |

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| EXAMINER | |
|---|---|
| BARHAM, BETHANY P | |

| ART UNIT | PAPER NUMBER |
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| 1615 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/505,393 | KUWANO ET AL. | |
| | Examiner | Art Unit | |
| | BETHANY BARHAM | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8,10,12,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10,12,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Summary*

Receipt of Applicant's response and claim amendments filed on 8/24/09 is acknowledged. Claims 8, 10, 12 and 18-19 are pending and rejected.

Due to Applicant's claim amendments the previous rejections of record are hereby withdrawn.

## NEW REJECTIONS

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8, 10, 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 6,395,294) in view of Wong et al (US 5,869,079).

The instant claims are drawn to a method of treating a disease of a posterior segment of an eye comprising administering subconjunctivally to a patient an effective amount for treatment of an injection comprising fine particles containing a drug and enabling the concentration of the drug in a retina-choroid to be sustained the disease of the posterior segment of the eye being uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy or retinal

detachment, the fine particles containing the drug being a matrix-type, wherein the drug is dispersed uniformly in the fine particles, and a particle diameter of the fine particles being 50 nm to 150 μm.

- Peyman discloses a drug delivery system (subconjunctival injection) to a posterior segment of an eye comprising fine particles containing a drug which are subconjunctivally administered, wherein the posterior segment of the eye is a vitreous body (col. 3, lines 12-27, 36-43; col. 4, lines 23-24, 33- 46). With respect to claim 8, Peyman discloses a method of treating a disease of a posterior segment of an eye (a surgical method to alleviate a structural disorder of the eye caused by the vitreous) comprising subconjunctivally administering to a patient an effective amount of an injection comprising fine particles containing a drug. Peyman discloses the structural disorder of the eye caused by the vitreous is uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion or central retinal artery occlusion. The particle size of Peyman is less than about 50 microns (col. 1, lines 14 - col. 2, line 25; col. 3, lines 12-27, 36-43; col. 4, lines 23-24, 33-46, 58-62).
- With respect to claims 10, Peyman discloses the therapeutic agent may be incorporated into a vesicle such as a microsphere made of polyglycolic or polylactic acid (biodegradable polymer) (col. 2, lines 52-54; col. 3, lines 36-42; col. 5, lines 38-44).
- With respect to claim 12, Peyman discloses the drug can be dexamethasone (anti-inflammatory/immunosuppressor), prednisone, triamcinolone, or

betamethasone (anti-inflammatory/immunosuppressor) (claim 1; col, 4, lines 45-46, 58- 61 ; col. 5, lines 4-19), which are the same drugs disclosed in the instant application. Therefore the drug is considered to be a drug for treatment/prevention of uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion or central retinal artery occlusion.

- Peyman does not teach that the fine particles are matrix type of instant claim 8.
- Wong et al teach compositions and methods of biodegradable implants that provide a controlled, sustained drug release (Col. 1, lines 66-68) with the particle size of spheres is taught to include 2 microns to 3 mm (col. 7, lines 50-51) and that the implants are preferably monolithic having the active agent homogenenously distributed through the polymeric matrix such as polylacitide (col. 5, lines 19-23 and 55-62) (meeting the limitations of claim 8).
- It is noted that instant claim 18 is a product-by-process claim and according to the MPEP 2113: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)". However, Wong et al does teach that the implants can be produced via interfacial methods (col. 8, line 6) and

according to the instant specification submerged drying method is the interfacial method (pg. 8, lines 6-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known method of treating and product of Peyman with the known technique of making a matrix-type particle of Wong et al with predictable results. A skilled artisan would know how to combine the known technique of Wong et al with the known method of treating and product of Peyman to yield predictable results.

Claim 8, 10, 12 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 6,395,294) in view of Wong et al (US 5,869,079) and further in view of US 6,264,970 ('970) or US 5,466,233 ('233).

- Peyman and Wong et al are taught above.
- With respect to claim 19, Peyman discloses the microparticles can comprise the drug can be betamethasone (anti-inflammatory/immunosuppressor) and the polymer polylactic acid (col. 5, lines 15 and 40-42)
- Peyman and Wong do not teach polylactic acid with a molecular weight of 20,000 of instant claim 19, but do teach a matrix particle comprised of polylactic acid and a drug such as betamethasone.
- '970 teaches that the microparticles comprising a polylactic acid matrix preferably have a molecular weight of 2,000 to about 20,000 (col. 5, lines 13-16, col. 14, lines 42-50).
- '233 teaches that the implant matrix includes homopolymers of polylactic acid from about 4,000 to about 100,000 molecular weight (col. 10, lines 5-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific molecular weight polylactic acid of '970 or '233 into the product of Peyman and Wong et al with predictable results. One of ordinary skill in the art would know how to optimize the ranges of '970 or '233, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." A skilled artisan would know how to substitute the generic polylactic acid of Peyman and Wong et al with the specific molecular weight polylactic acid of '970 or '233 to yield predictable results.

***Response to Arguments***

Applicant's arguments with respect to claims 8, 10, 12 and 18-19 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant amended claim 8 to include "matrix-type" fine particles with the drug uniformly dispersed in the particle and as such the previous 102 rejections of record are withdrawn and a new 103 rejection made.

***Conclusions***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-61755. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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